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10/016,323	12/10/2001	Derek J. Hei	282172000404	7855

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/016,323	Hei-Ro
Examiner	**Group Art Unit**
Kaplan	1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 4/11/03.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 58-104 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 58-104 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The preliminary of 4/11/03 amended the specification and claims 82-84, 86, 87 and 89, and added new claims 98-104.

Claims examined on the merits are 58-104 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 104 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to disclose a surface area as claimed. According to the specification at page 22, lines 14-15, the surface area of from about 300 to about 1100 m^2/g is internal surface area. Therefore, in line 2 of claim 104, "a" should be replaced with -- an internal --.

Claim Rejections - 35 USC § 112

Claim 104 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is confusing by reciting "An apparatus" in line 1 since the claims on which claim 104 depend require a system. It is suggested that "An apparatus" be replaced with -- A system --.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 98-103 are rejected under 35 U.S.C. 102(e) as being anticipated by Foley et al (6,319,662) or Lee (6,228,995).

The claims are drawn to a biological composition produced by the method of claim 82, 83, 84, 86, 87 or 89.

Foley et al and Lee are described below.

A blood product resulting from the process of Foley et al or Lee will be the same as the biological composition of the present claims when the composition is a blood product. No distinguishable difference is seen between a blood product resulting from the method of Foley et al or Lee as compared to a blood product resulting from methods on which claims 98-103 depend.

Claim Rejections - 35 USC § 103

Claims 58-73, 75-78, 81-85 and 87-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al (6,319,662) or Lee

(6,228,995) in view of Groeger et al (5,605,746) and Samejima (4,160,059) for reasons in the previous office action of 1/13/03 and for reasons herein.

The claims are drawn to a pathogen-inactivating compound adsorption system for reducing the concentration of a low molecular weight pathogen-inactivating compound in a biological composition. The system contains a housing compatible with the biological composition containing porous adsorbent resin particles having a particle diameter of about 1 μm to about 200 μm immobilized by a matrix. The particles have an affinity for the pathogen-inactivating compound and the system is configured to remove the pathogen-inactivating compound from the biological composition in a flow process, and so that the biological composition treated with the system maintains sufficient biological activity to be suitable for infusion within a human. Also claimed are method of using the system to treat a biological composition, and compositions resulting from the methods.

Foley et al disclose adding a viral inactivating agent such as a psoralen compound for virus inactivation in a body fluid such as a blood product, and then removing the agent from the blood product with an adsorptive material (col 4, line 42 to col 5, line 61). The adsorptive material may be beads having a particle size of 30-2000 μm, an average pore diameter of 45-300 angstroms, and a surface area of 150-1600 sq. meters/gram dry bead (col 5, lines 18-20). The beads are enclosed in a container, cartridge or other means for housing the beads (col 2, lines 30-33, and col 4, lines 43-47) through which the blood product passes.

Lee discloses using adsorbent beads to remove viral inactivating agents such as psoralens and psoralen degradation products from a blood product by passing the blood product through a cartilage containing the beads (col 2, lines 23-37, and Figures 2 and 3). The beads can have a diameter of 0.1 to 2 mm (100-2000 μm) (col 2, line 31).

Groeger et al disclose (col 3, lines 11-22) a fibrous structure containing a composite fiber matrix loaded with adsorbent functional particles such as activated carbon beads (col 5, line 50). The particles may have a size of 1 micron to 3-5 mm depending on the web structure (col 6, lines 12-30). A preferred size for activated carbon particles is about 400 to 500 microns (col 6, line 19). The fibrous structure has applications such as preparing high purity water, and for color or byproduct removal from whiskey and vinegar (col 10, lines 25-27).

Samejima discloses a fiber matrix loaded with an adsorptive material such as activated carbon (col 1, lines 11-39). Activated carbon has a surface area of 800-1800 m^2/gm (col 1, line 29). The adsorptive material may have various uses including purification of tap water (col 1, lines 35-36).

It would have been obvious to provide the adsorbent beads of Foley et al or Lee within a matrix as taught by Groeger et al and Samejima to obtain an expected advantage of the matrix holding the beads to prevent bead migration and bead abrasion, to provide three dimensional distribution and spacing of the beads, to facilitate handling of the beads and separation of the beads from a blood product, and to obtain the function of the matrix as an adsorbent in addition to the beads or as a

filter. The container or cartridge of Foley et al and Lee which contains the beads provides a housing for the beads. The adsorbent beads in the container or cartridge of Foley et al and Lee are used to treat a blood product to produce a blood product for infusing into a patient (Foley et al (col 3, lines 5-15) and Lee (col 3, lines 35-36). A blood product treated as disclosed by Foley et al or Lee inherently has sufficient activity to be infused into a human as claimed. When using a matrix such as a fibrous matrix to hold the beads, it would have been obvious to use a matrix that results in a blood product suitable for infusion into a human since this is an objective of Foley et al and Lee. Furthermore, the particle-containing matrix of Groeger et al or Samejima can be used for purifying water or liquids to be consumed by a human, and such a matrix would appear to be capable of providing a blood product suitable for infusing into a human. The conditions of dependent claims would have been matters of obvious choice within the skill of the art in view of the disclosures of the references and knowledge common in the art.

Response to Arguments

Applicants point out that the claimed system as a whole must be considered and that there must be motivation to combine the references. However, Foley et al and Lee disclose a system and method as claimed except for having the particles immobilized in a matrix. The secondary references disclose particles that can be the same as claimed immobilized in a matrix for use as an adsorptive material to purify a consumable liquid such as water. Groeger et al, in particular, disclose (col 4, lines 63-67 and col 6, lines 45-65) advantages of having the particles in

a matrix including three dimensional distribution and spacing of the particles, limiting migration of the particles and abrasive loss of particles, and the matrix in addition to the particles functioning to remove undesirable materials. These advantages would have been motivation to immobilize the particles of Foley et al or Lee in a matrix. Applicants have established no unexpected result in immobilizing the particles of Foley et al or Lee in a matrix.

It is granted as urged by applicants that Groeger et al and Samejima, as well as Foley et al and Lee, may use a particle size outside the claimed particle size range. However, these references may also use particles inside the claimed range, and it would have been obvious to use any of the particles sizes disclosed by the references. While Samejima does not disclose a particle size, the activated carbon used by Samejima is particulate and would have a size within the claimed range.

Even if Foley et al did not observe fines and Lee discloses that stainless steel screens effectively retain the particles, it would have been obvious to immobilize the particles in a matrix as suggested by Groeger et al and Samejima to obtain advantages of three dimensional distribution and spacing of the particles, preventing particle migration, and the matrix providing a separation function in addition to the particles. Furthermore, particles in a matrix would have an advantage of being easier to handle as suggested by Samejima (col 1, lines 55-65).

Applicants point to claim 59 as requiring a sintered polymeric matrix not being disclosed in the references. However, Groeger et al disclose using thermal bonding by using thermoplastic polymers to bond

fibers together and to bond fibers to the particles (col 3, lines 32-37 and col 11, lines 11-16). This melt bonding would be sintering as disclosed in the present specification. Also, Samejima uses heat-fusible fibers (col 4, line 25), and the use of heat-fusible fibers is to bond the fibers together by partial melting of the fibers. The present claims do not exclude a fibrous matrix prepared by thermal bonding as suggested by the secondary references.

While Groeger et al and Samejima may be adsorbing materials from ingestible products such as whisky, cider and water, the advantages of having particles in a matrix would have been expected to be obtained when adsorbing viral inactivating agents in blood as disclosed by Foley et al or Lee.

Claim Rejections - 35 USC § 103

Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85 and 87-104 above, and further in view of Davankov et al for reasons in the previous office action.

The claim requires the adsorbent resin particles to be hypercrosslinked.

Davankov et al disclose the use of hypercrosslinked polystyrene particles as an advantageous adsorbent to remove toxicants from blood.

It would have been obvious to use the hypercrosslinked polystyrene particles of Davankov et al for their expected advantage as the adsorbent beads of Foley et al or Lee when the beads are in a matrix as suggested by Groeger et al and Samejima.

Claim Rejections - 35 USC § 103

Claims 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85 and 87-104 above, and further in view of Horowitz et al (6,294,361) for reasons in the previous office action.

The claims require the resin particles to have affinity for a nucleic acid-binding compound having an electrophilic group that reacts with a nucleophilic group of a quencher.

Horowitz et al discloses (col 7, line 57 to col 8, line 16) the use of a quencher when inactivating a virus in blood with a psoralen compound.

When providing the beads of Foley et al or Lee in a matrix for removing a viral-inactivating agent such as a psoralen compound from a blood product as set forth above, it would have been obvious use a quencher for its expected function as taught by Horowitz et al, and the reacting of an electrophilic group of the psoralen compound with a nucleophilic group of the quencher would have been inherent.

Claim Rejections - 35 USC § 103

Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 58-73, 75-78, 81-85 and 87-104 above, and further in view of Wollowitz et al (5,593,823) for reasons in the previous office action.

The claim requires specific psoralen compounds as the pathogen-inactivating compound.

Wollowitz et al disclose psoralen compounds that have improved pathogen-inactivating activity in blood that can be the same as presently claimed. For example, see the paragraph bridging cols 4 and 5, and col 65, lines 35-51.

When providing the beads of Foley et al or Lee in a matrix for removing a viral-inactivating agent from a blood product as set forth above, it would have been obvious to use the psoralen compounds of Wollowitz et al as the psoralen compound to obtain their improved pathogen inactivating activity.

Response to Arguments

In response to the rejections of claims 74, 79, 80 and 86 above, applicants assert that these claims are dependent on claim 58, and are patentable for the same reasons presented in regard to claim 58. However, for reasons set forth above, claim 58 is still considered obvious.

Double Patenting

Claims 58-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53-110 of copending Application No. 09/972,323 in view of Foley et al or Lee for reasons in the previous office action.

The claimed invention, Foley et al and Lee are described above.

The claims of the copending application are drawn to a method of reducing the concentration of a low molecular weight compound in an aqueous biological composition by contacting the composition batchwise with an adsorption medium comprising porous absorbent particles

immobilized by a matrix wherein the particles have a diameter ranging from about 100μm to about 1500 μm to adsorb the low molecular weight compound.

It would have been obvious to enclose the matrix and adsorbent particles of the device of the copending application claims in a flow through housing as suggested by Foley et al or Lee using adsorbent beads in a flow through housing to obtain continuous flow when removing a viral inactivating agent from a blood product.

This is a provisional obviousness-type double patenting rejection.

Double Patenting

Claims 58-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53-115 of copending Application No. 10/011,202 in view of Foley et al or Lee.

The claimed invention, Foley et al and Lee are described above.

The claims of the copending application are drawn to a pathogen-inactivating compound adsorption system for reducing the concentration of a low molecular weight pathogen-inactivating compound in a biological composition containing cellular elements. The system contains a housing compatible with the biological composition containing porous adsorbent particles having a particle diameter of about 100 μm to about 1500 μm immobilized by a matrix. The particles have an affinity for the pathogen-inactivating compound and the system is configured to remove the pathogen-inactivating compound from the biological composition in a batch process, and so that the cellular elements of the biological composition

treated with the system maintain sufficient biological activity so that the biological composition is suitable for infusion within a human. Also claimed is a method of using the system to treat a biological composition.

It would have been obvious to provide the matrix and adsorbent particles in the housing of the system of the copending application claims for flow through the housing instead of for a batch process as suggested by Foley et al or Lee using adsorbent beads in a flow through housing to obtain continuous flow when removing a viral inactivating agent from a blood product.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicants indicate they are willing to file a terminal disclaimer in a later allowed application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from

the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
6/27/03